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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/708,964 | 11/08/2000 | Philip A. Beachy | JHUC-P04-010 | 3944 |

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| EXAMINER |
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BADIO, BARBARA P

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,964

Applicant(s)

BEACHY ET AL.

Examiner

Barbara P Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,2,15-23,25 and 27-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1,2,15-23,25 and 27-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 1, 15-17, 20-23, 27, 28 and 36, drawn to a method for inhibiting unwanted activation of a hedgehog-patched pathway utilizing compounds having the basic chemical skeleton as veratramine, classified in class 514, subclass 277+.
 - 2. Claims 1, 15-17, 20-23, 27, 28 and 36, drawn to a method for inhibiting unwanted activation of a hedgehog-patched pathway utilizing compounds having the basic chemical skeleton as cyclopamine or jervine, classified in class 514, subclass 277+.
 3. Claims 1, 15-17, 20-23, 27, 28 and 36, drawn to a method for inhibiting unwanted activation of a hedgehog-patched pathway utilizing compounds having the basic chemical skeleton as muldamine, classified in class 514, subclass 172+.
 4. Claims 1, 15-17, 20-23, 27, 28 and 36, drawn to a method for inhibiting unwanted activation of a hedgehog-patched pathway utilizing compounds having the basic chemical skeleton as zygacine or verticine, classified in class 514, subclass 277+.
 5. Claims 1, 15-17, 20-23, 27, 28 and 36, drawn to a method for inhibiting unwanted activation of a hedgehog-patched pathway utilizing compounds

Art Unit: 1616

having the basic chemical skeleton as solanidine or chaconine, classified in class 514, subclass 172+.

6. Claims 1, 15-17, 20-23, 27, 28 and 36, drawn to a method for inhibiting unwanted activation of a hedgehog-patched pathway utilizing compounds having the basic chemical skeleton as tomatidine, classified in class 514, subclass 172+.
7. Claims 1, 15-17, 20-23, 27, 28 and 36, drawn to a method for inhibiting unwanted activation of a hedgehog-patched pathway utilizing compounds having the basic chemical skeleton as spirosolane, classified in class 514, subclass 172+.
8. Claims 1, 15-17, 20-23, 27, 28 and 36, drawn to a method for inhibiting unwanted activation of a hedgehog-patched pathway utilizing compounds not covered by Groups 1-7, classified in class 514, subclass 172+.
9. Claims 2 and 15-19, drawn to a method for inhibiting an altered growth state of a cell utilizing compounds having the basic chemical skeleton as veratramine, classified in class 514, subclass 277+.
10. Claims 2 and 15-19, drawn to a method for inhibiting an altered growth state of a cell utilizing compounds having the basic chemical skeleton as cyclopamine or jervine, classified in class 514, subclass 277+.
11. Claims 2 and 15-19, drawn to a method for inhibiting an altered growth state of a cell utilizing compounds having the basic chemical skeleton as muldamine, classified in class 514, subclass 172+.

Art Unit: 1616

12. Claims 2 and 15-19, drawn to a method for inhibiting an altered growth state of a cell utilizing compounds having the basic chemical skeleton as zygacine or verticine, classified in class 514, subclass 277+.
13. Claims 2 and 15-19, drawn to a method for inhibiting an altered growth state of a cell utilizing compounds having the basic chemical skeleton as solanidine or chaconine, classified in class 514, subclass 172+.
14. Claims 2 and 15-19, drawn to a method for inhibiting an altered growth state of a cell utilizing compounds having the basic chemical skeleton as tomatidine, classified in class 514, subclass 172+.
15. Claims 2 and 15-19, drawn to a method for inhibiting an altered growth state of a cell utilizing compounds having the basic chemical skeleton as spirosolane, classified in class 514, subclass 172+.
16. Claims 2 and 15-19, drawn to a method for inhibiting an altered growth state of a cell utilizing compounds not covered by Groups 9-15, classified in class 514, subclass 172+.
17. Claim 25, drawn to a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as veratramine, classified in class 514, subclass 277+.
18. Claim 25, drawn to a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as cyclopamine or jervine, classified in class 514, subclass 277+.

Art Unit: 1616

19. Claim 25, drawn to a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as muldamine, classified in class 514, subclass 172+.
20. Claim 25, drawn to a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as zygacine or verticine, classified in class 514, subclass 277+.
21. Claim 25, drawn to a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as solanidine or chaconine, classified in class 514, subclass 172+.
22. Claim 25, drawn to a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as tomatidine, classified in class 514, subclass 172+.
23. Claim 25, drawn to a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as spirosolane, classified in class 514, subclass 172+.
24. Claim 25, drawn to a pharmaceutical preparation utilizing compounds not covered by Groups 17-23, classified in class 514, subclass 172+.
25. Claims 29 and 30, drawn to a method for inhibiting unwanted hair growth utilizing compounds having the basic chemical skeleton as veratramine, classified in class 514, subclass 277+.

Art Unit: 1616

26. Claims 29 and 30, drawn to a method for inhibiting unwanted hair growth utilizing compounds having the basic chemical skeleton as cyclopamine or jervine, classified in class 514, subclass 277+.
27. Claims 29 and 30, drawn to a method for inhibiting unwanted hair growth utilizing compounds having the basic chemical skeleton as muldamine, classified in class 514, subclass 172+.
28. Claims 29 and 30, drawn to a method for inhibiting unwanted hair growth utilizing compounds having the basic chemical skeleton as zygacine or verticine, classified in class 514, subclass 277+.
29. Claims 29 and 30, drawn to a method for inhibiting unwanted hair growth utilizing compounds having the basic chemical skeleton as solanidine or chaconine, classified in class 514, subclass 172+.
30. Claims 29 and 30, drawn to a method for inhibiting unwanted hair growth utilizing compounds having the basic chemical skeleton as tomatidine, classified in class 514, subclass 172+.
31. Claims 29 and 30, drawn to a method for inhibiting unwanted hair growth utilizing compounds having the basic chemical skeleton as spirosolane, classified in class 514, subclass 172+.
32. Claims 29 and 30, drawn to a method for inhibiting unwanted hair growth utilizing compounds not covered by Groups 25-31, classified in class 514, subclass 172+.

Art Unit: 1616

33. Claims 31-35, drawn to a method for inhibiting unwanted cell proliferation utilizing compounds having the basic chemical skeleton as veratramine, classified in class 514, subclass 277+.
34. Claims 31-35, drawn to a method for inhibiting unwanted cell proliferation utilizing compounds having the basic chemical skeleton as cyclopamine or jervine, classified in class 514, subclass 277+.
35. Claims 31-35, drawn to a method for inhibiting unwanted cell proliferation utilizing compounds having the basic chemical skeleton as muldamine, classified in class 514, subclass 172+.
36. Claims 31-35, drawn to a method for inhibiting unwanted cell proliferation utilizing compounds having the basic chemical skeleton as zygacine or verticine, classified in class 514, subclass 277+.
37. Claims 31-35, drawn to a method for inhibiting unwanted cell proliferation utilizing compounds having the basic chemical skeleton as solanidine or chaconine, classified in class 514, subclass 172+.
38. Claims 31-35, drawn to a method for inhibiting unwanted cell proliferation utilizing compounds having the basic chemical skeleton as tomatidine, classified in class 514, subclass 172+.
39. Claims 31-35, drawn to a method for inhibiting unwanted cell proliferation utilizing compounds having the basic chemical skeleton as spirosolane, classified in class 514, subclass 172+.

Art Unit: 1616

40. Claims 31-35, drawn to a method for inhibiting unwanted cell proliferation utilizing compounds not covered by Groups 33-39, classified in class 514, subclass 172+.
41. Claim 37, drawn to a method for preparing a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as veratramine, classified in class 514, subclass 277+.
42. Claim 37, drawn to a method for preparing a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as cyclopamine or jervine, classified in class 514, subclass 277+.
43. Claim 37, drawn to a method for preparing a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as muldamine, classified in class 514, subclass 172+.
44. Claim 37, drawn to a method for preparing a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as zygacine or verticine, classified in class 514, subclass 277+.
45. Claim 37, drawn to a method for preparing a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as solanidine or chaconine, classified in class 514, subclass 172+.
46. Claim 37, drawn to a method for preparing a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as tomatidine, classified in class 514, subclass 172+.

Art Unit: 1616

47. Claim 37, drawn to a method for preparing a pharmaceutical preparation utilizing compounds having the basic chemical skeleton as spirosolane, classified in class 514, subclass 172+.
48. Claim 37, drawn to a method for preparing a pharmaceutical preparation utilizing compounds not covered by Groups 41-47, classified in class 514, subclass 172+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions 1-8 (9-16, 25-32 and 33-40) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different effects (i.e., they are drawn to different methods of using the claimed compounds).
3. Inventions 1-8, 9-16, 17-24, 25-32, 33-40 and 41-48 are drawn to methods of using, pharmaceutical preparations or method of making a pharmaceutical preparation comprising structurally different compounds.
4. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

Art Unit: 1616

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from within the elected Group for search purposes, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Art Unit: 1616

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
February 28, 2002